UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

TECHNICAL REVIEW BRANCH
DER for acute toxicity studies for 7969-EUP-UU

24/JAN/2013

MEMORANDUM

Subject:	Name of Pesticide Product:	Engenia™ Herbicide
	EPA Reg. No. /File Symbol:	7969-EUP-UU
	DP Barcode:	D407507
	Decision No:	469265
	Action Code:	R220
	PC Codes:	100094

From: David Lieu, Chemist
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505P)

01/29/2013
Byron T. Backus
Jan-29-2013

Through: Technical Review Branch (TRB)
Registration Division (7505P)

To: Michael Walsh, RM Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
N,N-Bis-(3-aminopropyl)methylamine salt of 3,6-dichloro-o-anisic acid*	60.80
Other Ingredient(s):	39.20
Total:	100.00%

* Contains 48.38% 3,6-dichloro-o-anisic acid (5 lbs acid equivalent per gallon or 600 grams per liter)

ACTION REQUESTED: The Risk Manager requests: "Please review all of the information for the Experimental Use Permit 7969-EUP-UU. Please note that this request is for use of Engenia Herbicide (7969-GUL). Please determine acceptability of data cited for this action."

BACKGROUND: BASF Corporation has applied for registration of an experimental use permit, EPA File Symbol 7969-EUP-UU. The submission includes a data matrix and company letter. BASF is submitting a proposal for a food use, crop destruct Experimental Use Permit (EUP) for Engenia herbicide (7969-GUL), to allow for field evaluations in soybean, cotton, wheat, corn and between crop applications. Engenia herbicide is a new dicamba based product that is being developed for use in dicamba tolerant crops, currently being developed by Monsanto. The EUP is required to evaluate field performance and to allow Engenia herbicide to be used as a dicamba tolerance selection tool during the production of dicamba tolerant crop seed.

RECOMMENDATIONS:

1. TRB reviewed the acute toxicity (6-pack) of the proposed product, 7969-EUP-UU and summarized the results below.

2. TRB does not concur with the registrant on the results of the dermal sensitization study and has concluded that the results were ambiguous. ^{3}H-thymidine incorporation increased significantly in some cases when the lymph node weights did not appear to increase. We recommend either the dermal sensitization study be repeated and resubmitted or Engenia™ Herbicide will be classified as a dermal sensitizer.

3. The acute toxicity profile for the proposed experimental use product, EPA File Symbol 7969-EUP-UU, is as follows:

acute oral toxicity	III	Acceptable	MRID 48599303
acute dermal toxicity	IV	Acceptable	MRID 48599304
acute inhalation toxicity	III	Acceptable	MRID 48599305
primary eye irritation	IV	Acceptable	MRID 48599306
primary skin irritation	IV	Acceptable	MRID 48599307
dermal sensitization	Positive	Acceptable	MRID 48599308

4. The proposed basic CSF submitted for 7969-EUP-UU must be reviewed and accepted by the TRB Product Chemistry Team.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 007969-EUP-00044

PRODUCT NAME: ENGENIA™ HERBICIDE

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if inhaled. Harmful if swallowed. Causes moderate eye irritation. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or using toilet. Avoid contact with eyes or clothing. Wear protective eyewear*. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A).
* [Protective eyewear may be specified, if appropriate.]

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If inhaled:
-Move the person to fresh air.
-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
-Call a poison control center or doctor for further treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA Evaluation Report for #7969-EUP-UU-

1. DP BARCODE: #407507

2. PC CODEs: 100094

3. CURRENT DATE: 01-23-2013

4. TEST MATERIAL: 3,6-Dichloro-2-methoxy benzoic acid, bis(3-aminopropyl)methylamine salt 60.8%; Dicamba/ 196095; BAS 1834 48.41% brown clear liquid; sp. grav. = 1.245.

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
OPPTS 870.1100-OECD 423 Acute oral toxicity / rat Bioassay Labor fuer biologische Analytik GmbH INF 515, 69120 Heidelberg / Study # 10-BF-OT078 and 10A0040/10X066/Nov-11-2010	48599303	LD_{50} Females is >2,000 mg/kg One out of six females died on study day 5 after the administration of 2,000 mg/kg. Clinical observations in all six animals revealed impaired general state, dyspnea, piloerection and ataxia from hour 0 until study day 3 after administration. Staggering, reduced feces and exsiccosis were observed in two animals between study day 1 and 3, while gasping was seen only in one animal on study day 1. The animal that died showed red discoloration of the forestomach.	III	A
OPPTS 870.1200-OECD 402 Acute dermal toxicity / rat Bioassay Labor fuer biologische Analytik GmbH INF 515, 69120 Heidelberg/ Study # 10-BF-DT079 and 11A0040/10X067/Sept-27-2010	48599304	LD_{50} Males /females> 5000 mg/kg No mortality occurred. No signs of systemic toxicity or skin effects were observed. Mean body weight of animals increased within the normal range throughout the study period. No macroscopic pathologic abnormalities were noted in the animals examined at the end of the study.	IV	A
OPPTS 870.1300-OECD 403 Acute inhalation toxicity / rat Experimental Toxicology and Ecology BASF SE 67056 Ludwigshafen, Germany/ Study # 13I0040/10I021 and 378813/Mar-24-2011	48599305	LC_{50} Males/females > 0.557 mg/L (MMAD between 1.2 and 3.8µm, GSD 3.2 to 5.8) No animals died at 0.294 mg/L. All death occurred at 1.052 and 5.045 mg/L. On study days 1-3 or 7-9. Clinical signs included accelerated respiration, labored respiration, intermittent respiration, abdominal respiration, respiration sounds, red encrusted eye, semiclosed eyelid, no defecation, poor general state, high stepping gait, piloerection and substance contaminated fur. In all mortalities body weights decreased until death. Gross pathological abnormalities included dark-red discoloration and edema of the lung and encrusted nose.	III	A
OPPTS 870.2400-OECD 405 Primary eye irritation / rabbit Seibersdorf Labor GmbH Toxicology 2444 Seibersdorf, Austria/ Study # SL-LT-388/10 BAS112 or 11H0040/10X068/Oct-04-2010	48599306	No corneal opacity or iritis. All eyes positive for conjuctival irritation (chemosis score of 2) at 1 hr; no positive scores for conjuactival irritation at 24 hrs or subsequently (only scores of 1 for redness and/or chemosis). All scores zero by day 7.	IV	A

OPPTS 870.2500-OECD 404 Primary dermal irritation / rabbit /Seibersdorf Labor GmbH Toxicology 2444 Seibersdorf, Austria Study #SL-LT-337/10 BAS111 or 18H0040/10X069/ Oct-04-2010	48599307	Not irritating No adverse skin reactions were observed in all animals at any examination term. PII was 0.0.	IV	A
OPPTS 870.2600-OECD 429 Dermal Sensitization- Local Lymph Node Assay/ mice /Experimental Toxicology and Ecology BASF SE 67056 Ludwigshafen, Germany Study #58V0040/10A148/ Feb-16-2011 /	48599308	Local Lymph Node Assay Ambiguous Positive control was appropriate. The undiluted test substance caused statistically significant increase in 3H-thymidine incorporation into the cells (increases slightly above S.I. of 3 for ^{3}H-thymidine incorporation for undiluted material). There was a statistically significant increase in some lymph node weights as well.	Positive	A